## **REMARKS**

The amendment to claim 1 corrects a minor error. The amendments to claims 6-8 serve to differentiate the subject matter defined from that of claim 1. The amendments to claims 62, 64, 65, 70 and 72 are made in response to the rejections under 35 USC § 112, first and second paragraphs. The language inserted in claims 62, 64 and 65 modifies one element of the methods claimed therein, which is the amount of compound of formula I that is administered to a mammal. All other elements of the processes defined by these claims remain unchanged.

The language deleted from claims 70 and 72 does not limit the scope of these claims.

Claims 1, 3, 4, 6-10, 18-27, 33-40, 42, 44, 45, 50-55, 58, 59, 62, 64, 65, 68-72, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting based on the following claims within copending applications:

- 1) claims 1–15 of copending application US 10/071,248, filed February 11, 2002, which claims priority to Application No. 60/115,877, filed January 13, 1999;
- 2) claim 61 of copending application US 09/948,915, filed September 10, 2001, which claims priority to Application No. 60/115,877, filed January 13, 1999;
- 3) claim 21 of copending application US 361,858, filed February 11, 2003, which claims priority to Application No 60/354,950, filed February 11, 2002.
  - 4) claim 12 of copending application US 10/086,417, filed March 4, 2003, which claims

priority to Application No. 60/115,878, filed January 13, 1999;

- 5) claim 74 of copending application US 09/993,647, filed November 27 2001, which claims priority to Application No.60/367,346, filed November 28, 2000;
- 6) claims 68, 74 and 80 of copending application US 10/042,203, filed January 12, 2002, which claims priority to Application No. 60/367,380, filed January 12, 2001;
- 7) claim 1, n=0, of copending application US 10/361,859, filed February 11, 2003, which claims priority to Application No 60/354937, filed February 11, 2002;
- 8) claim 2 of copending application US 10/308,187, filed December 3, 2002, which claims priority to Application No.60/334,609, filed December 3, 2001; and
- 9) claims 1-8 of copending application US 10/895,985 filed July 22, 2004, which claims priority to Application No.60/489,102, filed July 22, 2003.

This provisional obviousness-type double patenting rejection should be the only outstanding rejection once the amendments above are entered. MPEP 804 (I)(B), provides guidance to Examiners on how to address obviousness-type double patenting issues where a "provisional" non-statutory obviousness-type double patenting rejection is the only rejection remaining in an application. Relevant portions of MPEP 804 (I)(B) read as follows:

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in >at least<one of the applications.

## >Nonstatutory Double Patenting Rejections

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the other later—filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later filed application, while the earlier—filed application is rejectable on other grounds, a terminal disclaimer must be required in the later—filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should then withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without the need of a terminal disclaimer. A terminal disclaimer must be required in the later—filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based on the other two, it is not sufficient to file a terminal disclaimer in only one application addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other.

The subject application was filed before copending applications US 10/361,858, 10/361,859, 10/308,187 and 10/895,985 and is therefore, the "earlier filed application" under MPEP 804 (I)(B) with respect to each of these applications. Based on the procedures set forth in MPEP 804 (I)(B), the nonstatutory "provisional" obviousness-type double patenting rejections based on these applications should be withdrawn without filing a terminal disclaimer in the subject application.

Applicants traverse the provisional obviousness-type double patenting rejection based on claims 1–15 of copending application US 10/071,248. Claims 1-15 of this application are directed to specific urea compounds which require hydroxy substituents or ester substituents based on the proviso that "at least one of X¹ to X² of formula I is OH or -OC(O)C<sub>1</sub>-C<sub>4</sub> alkyl." The compounds claimed herein do not have hydroxy or ester groups at the positions corresponding to X¹ to X² of formula I within US 10/071,248. Applicants submit such compounds do not render the compounds claimed herein obvious. The examiner has not provided any evidence of motivation to eliminate the required substituents of the compounds claimed in US 10/071,248 to arrive at the compounds claimed herein.

Applicants will cancel the claims on which the rejection is based in copending applications 09/948,915 (claim 61) and 10/086,417 (claim 12) and submit copies of these amendments in supplemental submissions. Applicants will also file a terminal disclaimer in the subject application naming copending applications US 10/042,203 and US 09/993,647 once the obviousness-type double patenting rejection based on copending application 10/071,248 is overcome.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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